§ 482.100 Condition of participation: Organ procurement.

The transplant center must ensure that the hospital in which it operates has a written agreement for the receipt of organs with an OPO designated by the Secretary that identifies specific responsibilities for the hospital and for the OPO with respect to organ recovery and organ allocation.

§ 482.102 Condition of participation: Patient and living donor rights.

In addition to meeting the condition of participation ''Patients rights'' requirements at § 482.13, the transplant center must protect and promote each transplant patient's and living donor's rights.

(a) *Standard: Informed consent for transplant patients.* Transplant centers must implement written transplant patient informed consent policies that inform each patient of:

(1) The evaluation process;

(2) The surgical procedure;

(3) Alternative treatments;

(4) Potential medical or psychosocial risks;

(5) National and transplant center-specific outcomes, from the most recent SRTR center-specific report, including (but not limited to) the transplant center's observed and expected 1-year patient and graft survival, national 1-year patient and graft survival, and notification about all Medicare outcome requirements not being met by the transplant center;

(6) Organ donor risk factors that could affect the success of the graft or the health of the patient, including, but not limited to, the donor's history, condition or age of the organs used, or the patient's potential risk of contracting the human immunodeficiency virus and other infectious diseases if the disease cannot be detected in an infected donor;

(7) His or her right to refuse transplantation; and

(8) The fact that if his or her transplant is not provided in a Medicare-approved transplant center it could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid for under Medicare Part B.

(b) *Standard: Informed consent for living donors.* Transplant centers must implement written living donor informed consent policies that inform the prospective living donor of all aspects of, and potential outcomes from, living donation. Transplant centers must ensure that the prospective living donor is fully informed about the following:

(1) The fact that communication between the donor and the transplant center will remain confidential, in accordance with the requirements at 45 CFR parts 160 and 164.

(2) The evaluation process;

(3) The surgical procedure, including post-operative treatment;

(4) The availability of alternative treatments for the transplant recipient;

(5) The potential medical or psychosocial risks to the donor;

(6) The national and transplant center-specific outcomes for recipients, and the national and center-specific outcomes for living donors, as data are available;

(7) The possibility that future health problems related to the donation may not be covered by the donor's insurance and that the donor's ability to obtain health, disability, or life insurance may be affected;

(8) The donor's right to opt out of donation at any time during the donation process; and

(9) The fact that if a transplant is not provided in a Medicare-approved transplant center it could affect the transplant recipient's ability to have his or her immunosuppressive drugs paid for under Medicare Part B.

(c) *Standard: Notification to patients.* Transplant centers must notify patients placed on the center's waiting list of information about the center that could impact the patient's ability to receive a transplant should an organ become available, and what procedures are in place to ensure the availability of a transplant team.

(1) A transplant center served by a single transplant surgeon or physician must inform patients placed on the center's waiting list of:

(i) The potential unavailability of the transplant surgeon or physician; and